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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	09/933,708
Filing Date	August 22, 2001
First Named Inventor	Thomas PICCARIELLO, et al.
Group Art Unit	1653
Examiner Name	To Be Assigned
Attorney Docket Number	54719.000028

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		Number	Kind Code ² (if known)				
JR	1	5183883		Tanaka et al.	02-02-1993	536/112	
JR	2	6309633		Ekwuribe et al.	10-30-2001	424/85.1	
JR	3	2001/0031873	A1	Greenwald et al.	10-18-2001	546/290	

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ₆
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
JR	4	WO	02/34237	A1	New River Pharmaceuticals, Inc.	05-02-2002		

OTHER DOCUMENTS - NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
			YES	NO
JR	5	International Search Report, dated September 3, 2003	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Examiner Signature

Jeffrey E Russell

Date Considered

March 15, 2004

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

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<p>Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid control number.</p> <p>Substitute for form 1449A/PTO</p> <p>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p><i>(use as many sheets as necessary)</i></p>				Complete if Known	
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				Filing Date	August 22, 2001
				First Named Inventor	Thomas PICCARIELLO, et al.
				Group Art Unit	1653
				Examiner Name	Jeffrey Russel
				Attorney Docket Number	54719.000028
Sheet	1	of	1		

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Examiner Signature	Jeffrey B. Russel	Date Considered	March 15, 2004
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Application Number	09/933,708
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First Named Inventor	Thomas PICCARIELLO et al.
Art Unit	1653
Examiner Name	Unassigned
Attorney Docket Number	54719.000028

Sheet 1 of 1

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
JER	U62	US- 5,891,459	04-06-1999	Cooke et al.	424/439
JER	U63	US- 4,457,907	07-03-1984	Porter	424/71
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

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		Country Code:	Number - Kind Code (if known)				YES	NO
JER	F5	WO	98-04277	02-05-1998	University of Pittsburgh of the Commonwealth System of Higher Education		<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>

EXAMINER SIGNATURE Jeffrey E. RussellDATE CONSIDERED March 15, 2004

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Sheet	1	of	2
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Attorney Docket Number	54719.000028
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U.S. PATENT DOCUMENTS

Class / Subject -

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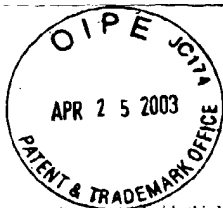
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Sheet 2 of 2

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Application Number	09/933,708
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JR	P49	CANARIS, G., "The Colorado Thyroid Disease Prevalence Study," Archives Internal Medicine Articles and Abstracts, Vol. 160, No. 4 (2000).	
JR	P50	BUNEVICIUS, R., "Effects of Thyroxine as Compared with Thyroxine Plus Triiodothyronine in Patients with Hypothyroidism," The New England Journal of Medicine, Vol. 340, No. 6 (1999).	
JR	P51	TOFT, A., "Thyroid Hormone Replacement -- One Hormone or Two?," The New England Journal of Medicine, Vol. 340, No. 6 (1999).	
JR	P52	PADE, V., et al., "Link Between Drug Absorption Solubility and Permeability Measurements in Caco-2 Cells," Journal of Pharmaceutical Sciences, Vol. 87, No. 12 (1998).	
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JR	P54	AMIDON, G., et al., "A Theoretical Basis for a Biopharmaceutic Drug Classification: The Correlation of <i>in Vitro</i> Drug Product Dissolution and <i>in Vivo</i> Bioavailability," Pharmaceutical Research, Vol. 12, No. 3 (1995).	

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Signature

Jeffrey E. Russell

Date
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U.S. PATENT DOCUMENTS

Class labels

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FOREIGN PATENT DOCUMENTS

Class/Subclass

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Jeffrey E. Russell

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Sheet 2 of 2

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First Named Inventor	Thomas Piccariello, et al.
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JR	P31	OKADA, Masahiko, et al., "Synthesis of Glycopeptide-Conjugates via Ring-Opening Polymerization of Sugar-Substituted α -Amino Acid N-Carboxyanhydrides (GlycoNCAs), <i>Proc. Japan Acad.</i> , 73:205-209, (1997).	
JR	P32	NISHIDA, Koyo, et al., "Pharmacokinetic Analysis of <i>in Vivo</i> Metabolism of Amino Acid of Dipeptide Conjugates of Salicylic Acid in Rabbit Intestinal Microorganisms", <i>Pharmaceutical Research</i> , 11(1):160-164 (1994).	
JR	P33	KAWAI, Tohru, "Direct Polymerization of N-Carboxy Anhydride of L-Glutamic Acid," <i>Makromol. Chem.</i> , 182:2127-2137 (1981).	
JR	P34	ZUNINO, Franco, et al., "Anti-Tumor Activity of Daunorubicin Linked to Poly L-Aspartic Acid," <i>Intl. J. Cancer</i> , 30:465-470 (1982).	
JR	P35	SCHMIDT, Bridtte F., et al., "Peptide-Linked 1,3-Dialkyl-3-acyltriazenes: Gastrin Receptor Directed Antineoplastic Alkylating Agents," <i>Journal of Medicinal Chemistry</i> , 37(22):3812-3817, (1994).	
JR	P36	KOVACS, J., et al., "Glutamic and Aspartic Anhydrides. Rearrangement of N-Carboxylglutamic 1,5-Anhydride to the Leuchs' Anhydride and Conversion of the Latter to Pyroglutamic Acid," 85:1839-1844.	

Examiner Signature	Jeffrey E. Russel	Date Considered	March 15, 2004
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		Number	Kind Code ² (if known)			
JSL	U1	3,846,399		Hirschmann et al.	11/05/74	530/342
JSL	U2	4,040,907		Ullman et al.	08/09/77	435/188
JSL	U3	4,356,166		Peterson et al.	10/26/82	525/541
JSL	U4	4,399,121		Albarella et al.	08/16/83	530/363
JSL	U5	4,552,864		Antoni et al.	11/12/85	514/115
JSL	U6	4,863,735		Kohn et al.	09/05/89	424/422
JSL	U7	4,976,962		Bichon et al.	12/11/90	424/424
JSL	U8	5,087,616		Myers et al.	02/11/92	514/21
JSL	U9	5,238,714		Wallace et al.	08/24/93	427/213.36
JSL	U10	5,534,496		Lee et al.	07/09/96	514/17
JSL	U11	5,762,909		Uzgrlis	06/09/98	424/9.31
JSL	U12	5,767,227		Latham et al.	06/16/98	530/324
JSL	U13	5,846,743		Janmey et al.	12/08/98	435/7.8
JSL	U14	5,851,536		Yager et al.	12/22/98	424/400
JSL	U15	5,882,645		Toth et al.	03/16/99	424/94.1
JSL	U16	5,910,569		Latham et al.	06/08/99	530/324
JSL	U17	5,948,750		Garsky et al.	09/07/99	514/2
JSL	U18	5,952,294		Lazo et al.	09/14/99	514/2
JSL	U19	5,977,163		Li et al.	11/02/99	514/449
JSL	U20	6,030,941		Summerton et al.	02/29/00	514/2
JSL	U21	6,306,993	B1	Rothbard et al.	10/23/01	526/304
JSL	U22	5,073,641		Bundgaard et al.	12/17/91	560/56

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JSL	F1	WO	97/36616		Seymour et al.	10/09/97		

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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JR	P1	ORTEN, James M. et al., "Thyroxine," <i>Human Biochemistry</i> , 9 th Ed., C.V. Mosby Company, St. Louis, pp. 401-405 (1975).	
JR	P2	LI, Chun, et al., "Complete Regression of Well-Established Tumors Using a Novel Water-Soluble Poly(L-Glutamic Acid)-Paclitaxel Conjugate," <i>Cancer Res</i> , 58:2404-2409 (1998).	
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JR	P5	MARRIQ, Claudine, et al., "Amino Acid Sequence of the Unique 3,5,3'-Triiodothyronine-Containing Sequence from Porcine Thyroglobulin," <i>Biochemical and Biophysical Research Communications</i> , 112(1):206-213 (1983).	
JR	P6	SAWADA, Kyoko, et al., "Recognition of L-Amino Acid Ester Compounds by Rat Peptide Transporters PEPT1 and PEPT2," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 291(2):705-709 (1999).	
JR	P7	DE VRUEH, Remco L.A., et al., "Transport of L-Valine-Acyclovir Via the Oligopeptide Transporter in the Human Intestinal Cell Line, Caco-2," <i>Journal of Pharmacology and Experimental Therapeutics</i> , 286(2):1166-1170 (1988).	
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JR	P9	BURNETTE, Thimysta C., et al., "Metabolic Disposition of the Acyclovir Prodrug Valaciclovir in the Rat," <i>Drug Metabolism and Disposition</i> , 22(1):60-64 (1994).	
JR	P10	AGGARWAL, et al., "Synthesis and Biological Evaluation of Prodrugs of Zidovudine," <i>J. Med. Chem.</i> , 33(5):1505-1511 (1990).	
JR	P11	ZUNINO, Franco, et al., "Comparison of Antitumor Effects of Daunorubicin Covalently Linked to Poly-L-Amino Acid Carriers," <i>European Journal of Cancer & Clinical Oncology</i> , 20(3):121-125 (1984).	
JR	P12	HAVRANOVA, Marie et al., "A High-Molecular Mass Derivative of Trypsin-Kallikrein Inhibitor for Potential Medical Use, II," <i>Hoppe-Seyler's Z. Physiol. Chem.</i> , 363:295-303 (1982).	
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JR	P14	HAN, Hyo-Kyung, et al., "Targeted Prodrug Design to Optimize Drug Delivery," <i>AAPS PharmSci</i> , 2(1): Article 6 (2000).	
JR	P15	TAMAI, I., et al., "Improvement of L-dopa Absorption by Dipeptidyl Derivation, Utilizing Peptide Transporter PepT1," <i>J. Pharma. Sci.</i> , 87(12):1542-1546 (1988), Abstract.	

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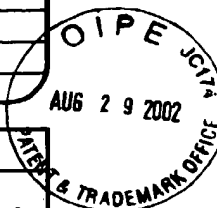
INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 5

Complete if Known

Application Number	09/933,708
Filing Date	August 22, 2001
First Named Inventor	Thomas PICCARIELLO, et al.
Group Art Unit	1653
Examiner Name	To Be Assigned
Attorney Docket Number	54719.000028



OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
JR	P16	OH, D.M., et al., "Drug Transport and Targeting. Intestinal Transport," <i>Pharma Biotechnol.</i> , 12:59-88 (1999), Abstract.	
JR	P17	BALIMANE, P., et al., "Effect of Ionization on the Variable Uptake of Valacyclovir via the Human Intestinal Peptide Transporter (hPePT1) in CHP cells," <i>Biopharm Drug Dispos.</i> , 21(5):165-174 (2000), Abstract.	
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JR	P19	SHEN, H., et al., "Developmental Expression of PEPT1 and PEPT2 in Rat Small Intestine, Colon, and Kidney," <i>Pediatr Res.</i> , 49(6):789-795 (2001), Abstract	
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JR	P21	HAN H., et al., "5'-Amino Acid Esters of Antiviral Nucleosides, Acyclovir, and AZT and Absorbed by the Intestinal PEPT1 Peptide Transporter," <i>Pharm Res.</i> , 15(8):1154-1159 (1998), Abstract.	
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JR	P27	LEIBACH, F.H, et al., "Peptide Transporters in the Intestine and the Kidney," <i>Annu Rev Nutri.</i> , 16:99-119 (1996), Abstract.	
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JR	P29	TOTH, Istvan, "A Novel Chemical Approach to Drug Delivery: Lipidic Amino Acid Conjugates," <i>Journal of Drug Targeting</i> , 2:217-239 (1994).	
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Examiner Signature	Jeffrey E. Russell	Date Considered	March 15, 2004
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